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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,355	07/18/2003	John Paul Mizzer	DCS-9129	5039

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DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,355

Applicant(s)

MIZZER ET AL.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-3-03</u> . | 6) <input type="checkbox"/> Other: ____ |

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1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The disclosure is objected to because of the following informalities: pages 6 and 8 have blank serial numbers for copending applications.

Appropriate correction is required.

3. Claims 3-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 3-4 the comparison basis is for the 33% or 50% increments is not clear: the original throughput rate or the rate after the first increment. Additionally it is not clear if the throughput increase is also tied to the number of reagents being dispensed: the increase is based on the number of tubes with a single dispenser and a single reagent. Looking at tables 1-3 of the instant specification, it appears that the basis is connected to the number of reagents required per assay and the number of reagent dispensers added. For examination purposes the claims will be treated as being met by a reference that adds dispensers for each reagent that is required to be added as the sample proceed through the device. In claim 6, it is not clear what constitutes an operating resource that is not throughput limiting. For examination purposes this limitation is being treated as there is space to added the additional reagent dispensers.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (US 3,615,239). In the patent Jones teaches an automated analyzer and its programmer. The

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analyzer has three parts, a transporter unit (A), a delivery unit or system (B) and the programming means(C). Column 2, lines 12-19 teach that the programming means is constructed in modular form, each module being representative of a single test or operation to be performed by the analyzer. Therefore, where the number of diagnostic tests to be performed by the analyzer is to be increased at some later date after installation of such a unit, it is a relatively simple matter to add a further module for programming the analyzer to perform the additional test. Column 4, lines 6-19 teach that a wide variety of tests may be performed, in general such tests require the addition of one or more reagents to the sample, a mixing of the reagents and the sample fluid, a period of incubation during which the test reaction may occur, and a final photometric analysis of the reaction mixture. In the apparatus disclosed, five treatment stations (26-30) are indicated *although a greater or smaller number may be provided depending on the number and type of different diagnostic tests to be performed*. At each of these stations, a predetermined quantity of a test reagent may be introduced into selected sample tubes from a suitable source of supply, one such source being indicated schematically at 31. Column 4 also describes the structure to add reagents at each station. In discussion the programming means, the first two paragraphs of column 7 further emphasize that the number of control modules and also the number of deliver stations depend on the size of the analyzer and the number of different treatment procedures to be performed.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berglund (US 4,459,265) or Minekane (US 4,906,433) in view of Jones as described above.

In the patent Berglund teaches an analysis apparatus in which one or, preferably, a plurality of reagent dispensing stations (R1-R3) are placed around a conveyor means. Column 2 lines 21-28 teach that the objective is to provide an apparatus that is relatively inexpensive, is of simple construction, requires a relatively small space and can be programmed to carry out a large number of different analyses on a larger number of samples which are supplied to the apparatus simultaneously. From the first full paragraph of column 3, the one or preferably a plurality of reagent-supply stations, capable of selectively supplying a plurality of different reagent liquids to the reaction tube advanced by the stepwise drivable conveyor or rotatable turntable, can supply each separate sample a large number of different reagent liquids and combinations thereof, thereby enabling the apparatus to carry out a large number of different analyses, by programming the reagent-supply stations to select a reagent liquid in dependence upon the desired analysis. Since each reagent-supply station only requires a single metering pump, the apparatus is of relatively simple construction and inexpensive, despite the large number of different analyses which can be carried out. The last paragraph of column 10 teaches that the apparatus can be modified and designed in a number of different ways, to suit the intended purpose. For example, the number of different reagent-supply stations, their mutual positions, and their positions relative to the positions of the sample-supply stations can be varied. Additionally, the number of possible reagent liquids in each reagent-supply station and the number of tubes on the turntable capable of being supplied by the reagent-supply station may be varied. Berglund does not teach modular configuration for the additional reagent-supply stations.

In the patent, figure 1 is a conventional automatic analyzer having a single reagent supply position. The first two full paragraphs of column 2 teach that due to the increasing amount and types of analyses being performed the number of reagents required is causing the reagent storage space to become expansive and the speed of the analyzer to become slowed by the time required to bring the reagent into a position that it can be withdrawn. The next paragraph teaches that the object is to allow the analyzer to perform high speed analysis regardless of the number of items to be analyzed and the quantities of reagent required for the analysis. This is accomplished by providing a plurality of reagent storage locations and reagent distribution means as shown in

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figures 2 and 4. The last full paragraph of column 7 before the claims teaches that various modifications can be made to include the number and position of the reagent vessel storage locations. Minekane does not teach a modular configuration for the additional reagent storage and supply locations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a modular configuration as taught by Jones for the additional reagent-supply stations or Berglund or the additional reagent storage and supply locations of Minekane because as shown by Jones the modular configuration facilitates the variation of reagents as needed by the number and type of analyses to be performed and the teaching by both Berglund and Minekane that the respective reagent supply means can vary in number and configuration.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to automated analyzers of various forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Arlen Soderquist

ARLEN SODERQUIST
PRIMARY EXAMINER